4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0104]

PolyMedica Industries Inc., et al.; Withdrawal of Approval of Three New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new drug applications (NDAs) from multiple holders of those NDAs. The basis for the withdrawal is that these NDA holders have repeatedly failed to file required annual reports for those NDAs.

DATES: Approval is withdrawn as of **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

FOR FURTHER INFORMATION CONTACT: Kimberly S. Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holder of an approved application to market a new drug for human use is required to submit annual reports to FDA concerning its approved application in accordance with § 314.81 (21 CFR 314.81).

In the *Federal Register* of March 3, 2021 (86 FR 12474), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of those NDAs because the holders of those NDAs had repeatedly failed to submit the required annual reports for those NDAs. The holders of the NDAs identified in table 1 did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes an election by those holders of the NDAs not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of their NDAs

and a waiver of any contentions concerning the legal status of the drug products. Therefore, FDA is withdrawing approval of the three applications listed in table 1.

Table 1.--Approved NDAs for Which Required Reports Have Not Been Submitted

Application No.	Drug	NDA Holder
NDA 016401	Neopap (acetaminophen) Suppositories, 120 milligrams (mg)	PolyMedica Industries Inc., 2 Constitution Way, Woburn, MA 01801
NDA 050266	Achromycin (tetracycline hydrochloride (HCl)) Ophthalmic Ointment, 10 mg/gram	Storz Ophthalmics Inc. (subsidiary of American Cyanamid Co.), 401 North Middletown Rd., Pearl River, NY 10965
NDA 050268	Achromycin (tetracycline HCl) Ophthalmic Suspension, 1%	Do.

FDA finds that the holders of the NDAs listed in table 1 have repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, FDA finds that the holders of the NDAs have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the NDAs listed in table 1 and all amendments and supplements thereto is hereby withdrawn as of **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

Dated: September 3, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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